

CLAIMS

1. A package (1) intended to be used to transport objects (2) which are sterile or to be sterilized, comprising a box (3) intended to accommodate objects (2) which are sterile or to be sterilized and a covering sheet (4) made of a selectively leaktight material, fastened onto the box (3) so as to seal the latter in a leaktight manner;

10 package (1) which comprises at least one layer (6, 8) of a material forming a screen which is at least partial with respect to a decontamination gas, for example, with respect to hydrogen peroxide vapor, and/or able to absorb a decontamination gas, for
15 example, hydrogen peroxide vapor, this layer (6, 8) having a shape and dimensions such that it can be placed in the box (3) along the covering sheet (4) and that it lies, in this position, above the objects (2) contained in the package (1), said layer or layers (6,
20 8), or the objects (2) being mobile between a diffusion position, allowing unrestricted diffusion of the sterilization gas over, between and possibly within the objects (2), and a nondiffusion position, enabling
restricted, or even prevented diffusion of the
25 decontamination gas, for example, the hydrogen peroxide vapor over, between and possibly within these same objects (2), and in that it further comprises a plate or a grid (20) provided with projections (21), shaped in order, in said diffusion position, to allow
30 unrestricted diffusion of the sterilization gas over, between and possibly within the objects (2), and, in said nondiffusion position, to restrict or prevent diffusion of the decontamination gas, for example of the hydrogen peroxide vapor over, between and possibly
35 within these same objects (2).

2. The package (1) as claimed in claim 1, characterized in that said layer or at least one of said layers is attached to the covering sheet,

especially by adhesive bonding or welding, and in that this layer or these layers are dimensioned so as to define, on the covering sheet, a peripheral region for fastening this covering sheet to the box.

5 3. The package (1) as claimed in claim 1, characterized in that said layer (6, 8) or at least one of said layers (6, 8) are arranged on the objects (2) placed inside the box (3), prior to sealing the covering sheet (4), or on supports provided to this
10 end, or on a part for positioning objects (2), placed in this box (3).

4. The package (1) as claimed in claim 1, which comprises at least one of said layers attached to the covering sheet and at least one other of said layers
15 arranged inside the box.

5. The package (1) as claimed in one of claims 1 to 4, which comprises several layers of material in order to form said screen.

6. The package (1) as claimed in claim 5,
20 characterized in that the layers of material forming said screen are identical from one layer to the other.

7. The package (1) as claimed in claim 5, characterized in that the layers of material forming

said screen are different from one layer to the other.

25 8. The package (1) as claimed in one of claims 1 to 7, characterized in that the layer or layers (6, 8) able to form said screen are shaped in order to define, when they are in place in the box (3), one or more lateral or peripheral openings or interstices between
30 their edges and the walls of this box (3).

9. The package (1) as claimed in claim 8, characterized in that said layer or layers (6, 8) have smaller dimensions than those of the box (3), such that they define one or more interstices between their edges
35 and the walls of this box (3).

10. The package as claimed in claim 8 or claim 9, characterized in that said layer or layers comprise, at their edges, notches and/or cutouts in the form of

pegs; such that they make openings between their edges and the walls of the box (3).

11. The package as claimed in any one of the preceding claims, characterized in that it is shaped
5 such that the layer or layers (6, 8) and/or the objects (2) go from the diffusion position to the nondiffusion position by gravity depending on whether the package (1) is placed in a first position corresponding to the diffusion position, or whether it is placed in a second
10 position, reversed with respect to said first position, corresponding to the nondiffusion position.

12. The package (1) as claimed in one of claims 1 to 11, which comprises two layers of the material marketed under the reference "TYVEK® 1073 B" by
15 DuPont de Nemours.

13. The package (1) as claimed in one of claims 1 to 11, which comprises two layers of medical grade paper, especially made of a material marketed under the name "STERISHEET®", "PROPYPEL®", "ETHYPEL®",
20 "ARPEEL®", "TALTER®" or "TRANSPHEL®" by Arjo Wiggins.

14. The package (1) as claimed in one of claims 1 to 11, which comprises two layers, one of which is made of a material marketed under the reference "TYVEK® 1073
B" by DuPont de Nemours and the other is made of a
25 medical grade paper, especially made of a material marketed under the names "STERISHEET®", "PROPYPEL®", "ETHYPEL®", "ARPEEL®", "TALTER®" or "TRANSPHEL®" by Arjo Wiggins.

15. The package (1) as claimed in one of claims 1
30 to 11, which comprises two layers, one of which is made of a material marketed under the reference "TYVEK® 1073 B" by DuPont de Nemours and the other is made of a material marketed under the reference "TYVEK® 2FS" by DuPont de Nemours.

35 16. The package (1) as claimed in one of claims 1 to 11, which comprises two layers, one of which is made of a material marketed under the reference "TYVEK® 2FS" by DuPont de Nemours and the other is made of a medical

grade paper, especially made of a material marketed under the names "STERISHEET®", "PROPYPEL®", "ETHYPEL®", "ARPEEL®", "TALTER®" or "TRANSPHEL®" by Arjo Wiggins.

5 17. The package (1) as claimed in claim 15 or claim 16, characterized in that the smooth side of the material marketed under the reference "TYVEK® 2FS" is placed in contact with the objects contained in the package.

10 18. A process of fabricating the package (1) as claimed in one of claims 1 to 17, which comprises the steps consisting in:

- using at least one material capable of forming a screen which is at least partial with respect to a
15 decontamination gas, for example with respect to hydrogen peroxide vapor, and/or capable of absorbing a decontamination gas, for example hydrogen peroxide vapor,

- making at least one layer (6, 8) of this material,
20 while choosing the shape and the dimensions of this layer (6, 8) such that the latter can be placed in the box (3) along the covering sheet (4) and that it lies, in this position, above the objects (2) contained in the package (1),

25 - making a plate or a grid (20) provided with projections (21) shaped in order, in a diffusion position, to allow unrestricted diffusion of the sterilization gas over, between and possibly within the objects (2), and, in a nondiffusion position, to
30 restrict or prevent diffusion of the decontamination gas, for example of the hydrogen peroxide vapor over, between and possibly within these same objects (2).

19. The process as claimed in claim 18, which comprises the steps consisting in:

35 - dimensioning said layer or at least one of said layers such that, when this layer is attached to the covering sheet (4), it defines on this covering sheet

(4) a peripheral region for fastening this covering sheet (4) to the box (3); and

- attaching said layer or at least one of said layers to the covering sheet (4), especially by adhesive bonding or welding.

20. The process as claimed in claim 18 or claim 19, which comprises the step consisting in arranging said layer or at least one of said layers (6, 8) on the objects (2) placed inside the box (3), prior to sealing the covering sheet (4), or on supports provided to this end, or on a part for positioning the objects (2), placed in this box (3).

21. The process as claimed in one of claims 18 to 19, which comprises the steps consisting in:

- dimensioning at least one of said layers such that, when this layer is attached to the covering sheet (4), it defines on this covering sheet (4) a peripheral region for fastening this covering sheet (4) to the box (3);
- attaching this layer or these layers or at least one of said layers to the covering sheet (4), especially by adhesive bonding or welding; and
- arranging at least one other of said layers on the

objects (2) placed inside the box (3), prior to sealing the covering sheet (4), or on supports provided to this end, or on a part for positioning the objects (2), placed in this box (3).

22. A sterilizing and decontamination process using the package (1) as claimed in claim 1, which comprises the steps consisting in:

- placing the package (1) in the diffusion position during the sterilization process; and
- placing the package (1) in the nondiffusion position during the decontamination process.

23. The sterilization and decontamination process using the package (1) as claimed in claim 11, which comprises the steps consisting in:

- placing the package (1) in a first position during the sterilization process, in which said layer or layers (6, 8) and the objects (2) are in the diffusion position, such that this layer or these layers
5 (6, 8) restrict only moderately, or even not at all, the diffusion of the sterilization gas over, between and possibly within the objects (2); and

- placing the package (1) in a second position during the decontamination process, in which said layer
10 or layers (6, 8) and the objects (2) are in the nondiffusion position, such that this layer or these layers (6, 8) restrict, or even prevent, the diffusion of the decontamination gas, for example, of the hydrogen peroxide vapor over, between and possibly
15 within these objects (2).

24. The use of the package (1) as claimed in one of claims 1 to 17 in a process for decontaminating this package by a decontamination gas, for example, by hydrogen peroxide vapor.

20 25. The use of the package (1) as claimed in one of claims 1 to 17 in order to transport syringe components, in particular syringe bodies (2) intended to be filled subsequently by an active product or a medication.
